UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

In re: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	MDL No. 2836
This Document Relates To: *Humana Inc. v. Merck & Co., Inc., et al.*, No. 2:21-cv-01007-RBS-DEM	Civil Action No. 18-md-02836-RBS-DEM **AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

PLAINTIFF HUMANA INC.'S AMENDED COMPLAINT

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Humana Inc. ("Humana" or "Plaintiff") brings this antitrust action against Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., and Schering Corp. (collectively, "Merck"); and Glenmark Pharmaceuticals Ltd. ("Glenmark", and with Merck, "Defendants"), seeking damages resulting from Defendants' anticompetitive conduct. Based on the investigation of counsel, and upon information and belief as to all other matters, Humana alleges as follows:

NATURE OF THE CASE

1. Heart disease is the leading cause of death in the United States, accounting for 1 out of every 4 deaths.[1] One of the major risk factors for heart disease is high cholesterol. In the United States, more than 93 million adults have cholesterol levels higher than 200 mg/dL and nearly 29 million have cholesterol levels exceeding 240 mg/dL.[2] Pharmaceutical companies have developed a litany of statins and other lipid-regulating drugs to treat this condition. And these companies have reaped enormous profits from their efforts. In 2011 alone, sales of cholesterol regulating drugs exceeded $39.1 billion per year.

2. Merck has developed and marketed several blockbuster cholesterol-reducing drugs. Indeed, two of its drugs — Zetia, the first drug in a new class of lipid-lowering medications, and Vytorin, a fixed-dosed combination pill comprised of Zetia and simvastatin (generic Zocor) — have been among the best-selling cholesterol treatment drugs over the past fifteen years, each consistently generating more than $1 billion in sales per year (and more than $2 billion in some years). As a result, when the new chemical exclusivity period on Zetia was

[1] *See* Centers for Disease Control and Prevention, *Heart Disease* (Oct. 22, 2020), available at https://www.cdc.gov/heartdisease/index.htm.

[2] *See* Centers for Disease Control and Prevention, *High Cholesterol Facts* (Sept. 8, 2020), available at https://www.cdc.gov/cholesterol/facts.htm.

nearing its end, and generic manufacturers were poised to enter with competing drugs, Merck took aggressive measures to protect its profits.

3. Seeing an opportunity to capitalize on Zetia's loss of exclusivity, Glenmark, a manufacturer of generic drugs, was the first company to file an Abbreviated New Drug Application ("ANDA") seeking to launch a generic to compete with Zetia. Shortly after the ANDA was filed, Merck sued Glenmark, alleging that Glenmark's generic would infringe a Merck patent allegedly covering Zetia. Merck later effectively admitted its lawsuit had no merit because it had failed to disclose prior art to the United States Patent and Trademark Office ("USPTO") that could have resulted in the denial of patent protection for Zetia. But simply by initiating the litigation, Merck triggered a 30-month stay, which precluded the Food & Drug Administration ("FDA") from granting final approval of Glenmark's ANDA.

4. Glenmark responded to Merck's lawsuit by asserting several meritorious affirmative defenses and counterclaims. Despite being put on notice of the various defects in its patent infringement claim, Merck did not dismiss its meritless litigation; rather, it continued to prosecute its action to blockade Glenmark's competition. During the course of the litigation, Merck and Glenmark discussed potential settlement. When they were unable to reach an agreement, Glenmark asked the court to rule on its pending motions for partial summary judgment. After the court granted in part and denied in part Glenmark's motions, Glenmark entered into a Marketing and Distribution Agreement (the "Distribution Agreement") with Par Pharmaceutical, Inc. ("Par"). Under the terms of the Distribution Agreement, Par would be the exclusive distributor for Glenmark's generic Zetia, and it would share in all potential Zetia settlement proceeds and profits on sales of Glenmark's generic Zetia in the United States.

5. Approximately seven days after Glenmark executed the Distribution Agreement with Par, Glenmark and Merck settled their action. This settlement, along with Merck's pursuit of litigation to enforce a patent it knew was invalid and/or unenforceable, was at the heart of Merck's — and now Glenmark's — anticompetitive scheme to deprive the market of generic competition for Zetia (and, by extension, Vytorin). Pursuant to their settlement agreement, Glenmark agreed to drop its meritorious claims and defenses against Merck and delay its launch of generic Zetia for nearly five years. In exchange, Merck agreed to refrain from competing with Glenmark by not introducing its own authorized generic ("AG") version of Zetia during Glenmark's 180-day period of first-filer exclusivity. Par played an integral role in negotiating these terms.

6. As a result of Merck's monopolistic scheme and its anticompetitive agreement with Glenmark, Merck reaped billions of dollars in additional sales of Zetia and Vytorin at monopoly prices. Glenmark also reaped millions of dollars in additional profits once its generic version of Zetia finally reached the market. Meanwhile, health plans, like Humana, were forced to significantly overpay for Zetia and Vytorin because there were no generic equivalents of Zetia and Vytorin. By the time Glenmark finally entered the market with its generic on December 12, 2016, Humana had overpaid by hundreds of millions of dollars for its members' Zetia and Vytorin prescriptions. And Humana continued to overpay, due to the delay-inflated drug prices and the lack of competition associated with Merck's agreement not to launch an AG.

7. If Merck had not failed to disclose prior art to the USPTO and not brought or maintained its frivolous patent litigation blocking generic competition, or Merck, Glenmark, and Par had not conspired to allocate the market for Zetia via their anticompetitive settlement agreement, both Merck and Glenmark would have launched generic versions of Zetia at least as

early as December 2011. And, six months later, additional generics would have entered the market, further driving down prices for branded Zetia. AB-rated generic entry of Zetia would have resulted in automatic substitution of generics for branded Zetia and Humana's members would have substituted lower-priced generic Zetia for higher-priced branded Zetia. In addition, Humana would have investigated the financial implications of mandating its members switch from branded Vytorin to generic ezetimibe and simvastatin and used its drug utilization management strategies, such as step policies or formulary placement, to encourage and/or require its members to substitute lower-priced generic Zetia and lower-priced simvastatin for higher-priced Vytorin.

8. Merck's overarching monopolistic scheme, Merck and Glenmark's anticompetitive settlement agreement, and Merck, Par, and Glenmark's unlawful business arrangement violated numerous State antitrust and consumer protection laws. Defendants were also unjustly enriched from their actions. Accordingly, Humana seeks damages for overcharges it paid as a direct result of Defendants' anticompetitive conduct.

PARTIES

9. **Humana.** Plaintiff Humana Inc. is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky 40202. Humana and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than 8 million members in all 50 States, the District of Columbia, and Puerto Rico. More than 75% of Humana's total premium revenues in the year 2012 were derived from contracts with the federal government, including Medicare Part D prescription drug coverage and Medicare Advantage plans. Humana operates its insurance businesses through a variety of

health plans and other subsidiaries, all of which have assigned their relevant claims in this action to Humana.[3]

10. At all times relevant to this Complaint, when any of Humana's members filled a prescription of Zetia, Vytorin, or their generic equivalents at a pharmacy, Humana — through its various health plans — has paid a large share of the cost of those drugs. For instance, over the relevant time period, Humana paid hundreds of millions of dollars to pharmacies for Zetia, generic Zetia, Vytorin, and generic Vytorin dispensed to its members in all 50 States, as well as the District of Columbia and Puerto Rico.

11. **Merck Defendants.** Merck & Co., Inc. is a corporation organized and existing under the laws of the state of New Jersey, with a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is or was the parent company of Merck Sharp & Dohme Corp. and MSP Singapore Co. LLC.

12. Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the state of New Jersey, with a principal place of business at 2000 Galloping Hill Road,

[3] Some of the subsidiaries, health plan and otherwise, through which Humana conducts insurance business and incurs expenses related to Zetia, generic Zetia, Vytorin, and generic Vytorin include the following entities: Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., PHP Companies, Inc., Cariten Health Plan Inc., CHA HMO, Inc., CompBenefits Insurance Company, Emphesys Insurance Company, Health Value Management, Inc. d/b/a ChoiceCare Network, Humana Benefit Plan of Texas, Inc., Humana Benefit Plan of Illinois, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc., Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health Plan, Inc., Humana Insurance Company, Humana Insurance Company of Kentucky, Humana Insurance Company of New York, Humana Medical Plan of Michigan, Inc., Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah, Inc., Humana Medical Plan, Inc., Humana Pharmacy Inc., Humana Pharmacy Solutions, Inc., Humana Regional Health Plan, Inc., Humana Wisconsin Health Organization Insurance Corporation, Humana Health Plans of Puerto Rico, Inc., Humana Insurance of Puerto Rico, Inc., and HumanaDental Insurance Company. These entities assign their relevant claims in this action to Humana Inc.

Kenilworth, New Jersey 07033. It is a subsidiary of Merck & Co., Inc. and the assignee of patents relevant to this lawsuit.

13. Schering-Plough Corp. ("Schering-Plough") was a corporation organized and existing under the laws of the state of New Jersey, with a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

14. Schering Corp. ("Schering") was a corporation organized and existing under the laws of the state of New Jersey, with a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It was a wholly owned subsidiary of Schering-Plough Corp. and the original assignee of the relevant patents.

15. In 2009, as part of Merck & Co., Inc.'s acquisition of Schering-Plough Corp., Merck & Co., Inc. merged into Schering-Plough Corp. Schering-Plough Corp. subsequently changed its name to Merck & Co., Inc., and the company originally known as Merck & Co., Inc. changed its named to Merck Sharp & Dohme Corp.

16. **Glenmark Defendant.** Glenmark Pharmaceuticals Limited is an Indian corporation with a principal place of business at Glenmark House, B.D. Sawant Marg, Andheri (E), Mumbai 400 099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

CO-CONSPIRATORS OF DEFENDANTS

17. Par Pharmaceutical, Inc. is a New York corporation with a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical, Inc. is a subsidiary of Endo International plc, an Irish corporation with a U.S. headquarters in Malvern, Pennsylvania. In September 2015, Endo completed its acquisition of Par Pharmaceutical Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with

Endo's existing generics subsidiary, Qualitest Pharmaceuticals. In this Complaint, "Par" refers to all of Par's predecessors and successors. Par conspired with Defendants to blockade and delay generic competition in order to enhance profits, in which it shared.

18. MSP Singapore Co. LLC is a company with a principal place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033. MSP Singapore Co. LLC is a subsidiary of Merck & Co., Inc. and was the exclusive licensee of the relevant patents.

19. Glenmark Pharmaceuticals Inc., USA is a corporation with a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is a wholly owned subsidiary of Glenmark Pharmaceuticals Limited. Since 2002, when Glenmark Pharmaceuticals Inc., USA was incorporated, the company has been referred to, done business as, and/or been known as both Glenmark Pharmaceuticals Inc., USA and, at times, Glenmark Generics Inc., USA.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a). This action is between citizens of different states and the amount in controversy exceeds $75,000.

21. This Court has general personal jurisdiction over Defendants because Defendants are either residents of New Jersey or have continuous and systematic connections with New Jersey as to render them essentially at home in the State. The Court also has specific personal jurisdiction over Defendants as they have purposefully availed themselves of the privilege of doing business in New Jersey and this action arises out of or relates to Defendants' contacts with New Jersey.

22. Venue is proper and appropriate in this district pursuant to 28 U.S.C. §1391. All of the Merck Defendants reside in this district, Glenmark conducts significant business in this

district through its wholly owned subsidiary Glenmark Pharmaceuticals Inc., USA, a substantial part of the events giving rise to the claim occurred in this district, and the Defendants are subject to the court's personal jurisdiction in this district.

FACTUAL BACKGROUND

A. The Regulatory Structure for Approval and Substitution of Generic Drugs.

23. The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act") provides regulatory exclusivity for new pharmaceuticals while providing a pathway for entry of low-priced generic drugs. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the new product, as well as any information on applicable patents. The products based on these NDAs are generally referred to as "brand-name drugs" or "branded drugs."

24. When the FDA approves a manufacturer's NDA, it lists certain information about any patents identified by the manufacturer as covering the new drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). Specifically, the FDA lists any patents that: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not listed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1) & (c)(2).

25. The FDA's listing of patents in the Orange Book is solely a ministerial act. The agency relies completely on a manufacturer's representations about patent validity and applicability, as it lacks resources and authority to verify the patents for accuracy and trustworthiness. When patents are issued after the FDA approves an NDA, a manufacturer may subsequently list the patents in the Orange Book, provided it does so within 30 days of the patent issuing.

26. A drug that receives NDA approval is entitled to regulatory exclusivity for a limited period of time — in other words, the FDA cannot approve any generic drug applications during this period.

1. The Hatch-Waxman Act and ANDA Approval Process.

27. When a branded drug's regulatory exclusivity is about to expire, a generic manufacturer may submit an ANDA that demonstrates that a generic version of the drug is essentially the same as the branded version: i.e., it has the same active ingredients, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

28. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Pursuant to Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

a. Paragraph I Certification: No patent for the branded drug has been filed with the FDA;

b. Paragraph II Certification: The patent for the branded drug has expired;

c. Paragraph III Certification: The patent for the branded drug will expire on a particular date, and the manufacturer does not seek to market its generic drug before that date; or

d. Paragraph IV Certification: The patent for the branded drug is invalid or will not be infringed by a generic manufacturer's proposed product.

29. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the generic manufacturer for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval of the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid, unenforceable, or not infringed by the generic manufacturer's proposed product. Until one of these two things occur, the FDA

may tentatively approve the ANDA, but it cannot authorize the generic manufacturer to market its product. The FDA may grant tentative approval of an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

30. To incentivize manufacturers to develop and seek approval of generic drugs, the Hatch-Waxman Act grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant to file a substantially complete ANDA (the "first-filer"). The first-filer's exclusivity period is measured from the date the generic drug is first commercially marketed or the date of a court decision finding the patent(s) which are the subject of the Paragraph IV certification to be invalid, unenforceable, or not infringed, whichever is earlier. During this exclusivity period, the first-filer can market and sell its generic free from competition with other generics, except that the brand manufacturer is permitted to launch its own AG. As a result, during the 180-day exclusivity period, the generic manufacturer effectively has a duopoly with the brand manufacturer.

31. Generic manufacturers frequently compete to be the first-filer in order to reap the benefits of the 180-day exclusivity period. Before a generic enters, a branded drug is typically priced far above competitive levels. Therefore, during the 180-day exclusivity period, the generic price (although lower than the branded price) is much higher than it would be in the presence of two or more generic competitors. This results in greater profits to the first-filer.

32. Generic drugs are typically at least 25% less expensive than their brand-name counterparts when there is a single generic competitor. This discount typically increases to 80-90% (or more) where there are multiple generic competitors on the market. For a generic manufacturer, being able to sell at a higher price for 180 days may equate to hundreds of millions of dollars in profits.

33. Under the Hatch-Waxman regulatory scheme, brand manufacturers have strong financial incentives to illegally prevent generic entry by listing patents in the Orange Book — even if those patents are not eligible for listing because they are invalid or unenforceable or, in some cases, do not even cover the product for which they are listed. Brand manufacturers also illegally block competition by suing any generic competitor that files an ANDA with a Paragraph IV certification, even if the generic manufacturer's product does not actually infringe a listed patent. This is because merely filing suit — even a baseless one — ensures a generic cannot enter the market during the automatic 30-month stay.

34. The first generic applicant can help the brand manufacturer's anticompetitive scheme by agreeing to delay its own market entry, which effectively blocks the market entry of all generic products because generic manufacturers who file after the first generic applicant cannot launch until the first applicant uses or forfeits its 180-day exclusivity period, even if the first generic applicant agrees to delay its launch for years.

2. Benefits of Generic Drugs.

35. Generic versions of brand-name drugs contain the same active ingredient as the branded drug and have been determined by the FDA to be just as safe and effective as the brand. ANDAs for orally available solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for FDA approval are assigned an "AB" rating. AB-rated generics are deemed by the FDA to be therapeutically and pharmacologically equivalent to their brand-name counterparts.

36. An AB-rating for a generic is significant because these drugs can be substituted at the pharmacy for branded drugs. All 50 states, the District of Columbia, and Puerto Rico have drug substitution laws that encourage and facilitate this type of substitution. When a pharmacist

fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense a generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.

37. Many health plans have adopted policies to encourage the substitution of lower cost generic drugs instead of their branded counterparts. Plans benefit from drug utilization policies, such as step therapy, prior authorization, and formulary tier placement[4], to encourage and/or mandate that members substitute higher-priced products for lower-priced products.

38. As Merck has publicly acknowledged: "Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product, as lower priced generic versions of that drug become available."[5]

39. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating lower-cost generic competition and generating significant savings for consumers and health plans. Until a generic manufacturer enters the market with an AB-rated generic product, there is no bioequivalent generic that competes with the branded drug, and the brand manufacturer can charge monopoly prices without the risk of losing all or a substantial portion of its sales.

40. When a generic drug enters the market, however, the branded drug often suffers a rapid, steep decline in sales. Generic drugs typically capture over 80% of a branded drug's sales within six months and take over 90% of the brand's unit sales. Generic drugs are also usually markedly cheaper than the branded version — with discounts often reaching 85% or more off the brand price. As more generic manufacturers enter the market, prices for generic versions of a

[4] Formularies are lists of prescription drugs covered by an insurer. Tiered formularies divide prescription drugs by cost, with the lowest tier costing the least and the highest tier costing the most.

[5] *See, e.g.*, Merck & Co., Inc., 2016 Annual Report (Form 10-K) 18 (Feb. 28, 2017), available at 0000310158-17-000010 (q4cdn.com).

drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates. Although competition from a generic typically generates substantial savings (sometimes billions of dollars per year for popular drugs) for patients, health plans, and federal and state governments, brand manufacturers are incentivized to stop generics from entering because generics pose a significant threat to their profits.

3. The Impact of Authorized Generics.

41. Although the 180-day exclusivity period for the first-filer precludes other generic manufacturers from entering the market, it does not prevent the brand manufacturer from marketing and selling its own generic during this period. The brand manufacturer's AG is identical to the branded drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Brand manufacturers do this in order to retain at least some of the sales that would otherwise be lost to the first-filer.

42. When a brand manufacturer launches an AG during the 180-day exclusivity period, it leads to lower prices for generic drugs and a decrease in sales of the branded drug. Indeed, the Federal Trade Commission has concluded that AGs capture a significant portion of sales and may reduce the first-filer's revenues by 40-52% during the 180-day exclusivity period.[6] Accordingly, the first-filer makes significantly less money when it faces competition from an authorized generic because: (1) the AG takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market leads to lower overall generic prices. Conversely, the lack of an AG harms competition by reducing consumer choice and allowing the first-filer to sell its generic at inflated prices.

[6] F.T.C., *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (Aug. 2011).

43. From a practical perspective, authorized generics are the only means by which brand manufacturers engage in price competition with generic manufacturers after generic entry. Brand manufacturers do not typically reduce the price of the branded drug in response to entry of a generic. Instead, during the relevant time period, brand manufacturers typically raise the brand-name price to extract higher profits from a small number of "brand-loyal" patients.

B. Economics of Reverse Payment Agreements.

44. Reverse payment agreements arise in response to a threat to a brand manufacturer's loss of exclusivity from patent challenges by generic drug makers. In a reverse payment agreement, the brand manufacturer pays the generic manufacturer to dismiss its patent challenge and forego generic entry for an agreed-upon period of time. Reverse payment agreements disrupt the well-established process by which generic competition reduces drug prices.

45. From an economic perspective, there is reason to scrutinize any reverse payment agreement because it arises in a unique context. In Hatch-Waxman litigation, the generic manufacturer does not claim damages from the brand manufacturer that holds the rights to the patent. As a result, a typical motivation for a settlement payment — to compensate for damages that have allegedly accrued — does not exist. Indeed, the very existence of the payment is an unusual feature of the agreement that requires explanation and invites careful scrutiny for its potential anticompetitive purpose and effect.

46. Absent the deterrent effect of antitrust law, reverse payment agreements would be economically rational for both the brand and generic drug manufacturers. By delaying generic entry, the brand manufacturer preserves a stream of monopoly profits. The brand manufacturer can use those profits to pay the generic manufacturer more than it would earn if it entered the

market and competed against the brand manufacturer's products (and any subsequent generic entrants). Although both companies profit from the arrangement, consumers and third-party payors lose because they are deprived the benefits of competition — including the opportunity to purchase lower-priced generics.

47. Reverse payment agreements that include a commitment by the brand manufacturer not to launch an AG (a "No-AG provision") are even more harmful to competition because, unlike cash payments, the No-AG provisions delay generic entry and continue to restrict competition after generic entry by eliminating competition between the generic manufacturer's product and the AG. The profits used by the brand manufacturer to compensate the generic manufacturer in a No-AG provision come from the pockets of purchasers, like Humana, who would otherwise pay the manufacturers less in the absence of a No-AG agreement.

CHOLESTEROL LOWERING DRUGS

48. Cholesterol is essential in constructing and maintaining membranes in animal cells, forming the myelin sheath that insulates nerve cells and facilitates conducting nerve impulses; it is also an important precursor for making vitamin D and steroid hormones in the body.

49. Our bodies derive cholesterol from two sources: we make it in our livers and absorb it through our intestines. This absorption includes both cholesterol from the foods we eat and the cholesterol we make. About 50% of the cholesterol made in our livers is reabsorbed through our intestines.

50. There are two types of cholesterol: low-density lipoprotein ("LDL") and high-density lipoprotein ("HDL"). HDL cholesterol is known as "good" cholesterol because, in high plasma concentrations, it helps prevent the development of atherosclerosis. LDL cholesterol,

produced in the liver, is known as "bad" cholesterol because, in high plasma concentrations, it promotes the development of atherosclerosis — a contributing factor to coronary heart disease.

A. Blocking the Liver's Production of Cholesterol — the Development of Statins.

51. In the 1970s and 1980s, scientists began researching ways to reduce the production of LDL in the liver. This research resulted in the development of statins.

52. One of Merck's statins, Zocor (simvastatin), launched in 1998 and became a blockbuster drug.

53. Statins, as a class, are the first-line treatment for patients with high LDL cholesterol and for many years were the most profitable drugs in pharmaceutical history. However, approximately 60% of the 13 million patients in the U.S. that take statins do not reach their target reduction in LDL cholesterol. There is also a subset of the statin-taking population who experience significant side effects. For these patients, statins are not a meaningful treatment option. As a result, pharmaceutical companies were incentivized to develop an alternative to statins to reduce LDL cholesterol.

B. Blocking the Absorption of Cholesterol — Zetia.

54. Looking to expand on its success with Zocor, and under pressure to develop another blockbuster drug, Merck entered into a joint venture with Schering-Plough to develop a series of cholesterol-lowering drugs. By the early 2000s, Merck and Schering-Plough developed Zetia, a drug that inhibits absorption of cholesterol through the intestine.[7] Zetia is not a statin.

[7] Zetia was discovered by Schering-Plough scientists and developed and marketed by Merck/Schering-Plough Pharmaceuticals, a joint venture formed in 2000 between Merck and Schering-Plough. *See* Merck/Schering-Plough Pharmaceuticals News Release, SEC Filing Ex. 99.2 (March 10, 2004).

55. Merck and Schering-Plough filed a New Drug Application ("NDA") for Zetia on December 27, 2001. The NDA sponsor is sometimes identified as Merck/Schering-Plough Pharmaceuticals and sometimes identified as MSP Singapore Co. LLC. The final printed labeling submitted with the NDA is marked "COPYRIGHT (c) Merck/Schering-Plough Pharmaceuticals," and states that the drug is "[m]anufactured for: Merck/Schering-Plough Pharmaceuticals … [b]y Schering Corporation." In correspondence, Schering is identified as the agent for MSP Singapore. During its review, the FDA corresponded with Schering, Schering-Plough, and Merck personnel, including at least Joseph F. Lamendola, Bernadette Mauser, Deborah Urquhart, Michael Perelman, Robert Silverman, and Enrico Veltri. According to correspondence, Merck & Co., Inc. and Schering-Plough Research Institute intended to disclose financial information for the NDA. The NDA was approved by the FDA on October 25, 2002, and Zetia entered the market later that same month.

56. Prior to the merger between Merck and Schering-Plough, the companies agreed to equally share development and promotional costs for Zetia and other jointly developed cholesterol drugs. Merck and Schering-Plough also equally shared profits on Zetia (and later Vytorin) in the U.S., with the exception of the first $300 million on Zetia, for which Schering-Plough received a greater share of the profits. After Merck and Schering merged, Merck became the sole owner of Zetia, Vytorin, and other jointly developed cholesterol drugs.

57. Zetia quickly became a steady source of enormous profits for Merck, with annual U.S. sales of approximately $1 billion in 2010 and $1.6 billion by 2016.

58. Zetia proved to be a blockbuster drug for Merck. Part of its appeal is that it works when taken alone or in combination with statins. For patients for whom statins were contraindicated (for example, patients who were at risk of impairing liver function or for whom

the side-effects were unbearable), Zetia may be used alone. And, where statins do not successfully lower a patient's LDL cholesterol to safe levels, Zetia can be used to complement the statins. Indeed, combining Zetia with a statin reportedly provides a significantly greater benefit (up to 25% more) than using only Zetia or a statin.

59. According to Merck, as of 2011, about half of Zetia prescriptions were for "statin-intolerant" patients and the other half were for patients who needed Zetia to complement their statin prescriptions.

C. Blocking the Absorption and Production of Cholesterol — Vytorin.

60. Merck released Vytorin on July 23, 2004 as a cholesterol-lowering therapy that combined Zetia and Zocor, or ezetimibe and a statin. As described above, Zetia was successful at blocking the absorption of cholesterol while Zocor reduced the production of LDL in the liver. While some patients experienced positive results from Zetia or Zocor, or another statin, alone, many others experienced significantly lower cholesterol levels by combining the two. Like the single pill alternatives that Merck offered, Vytorin too was a blockbuster drug for patients who took Zetia and Zocor to treat hyperlipidemia.

61. Merck asserted two patents to protect its Vytorin monopoly: U.S. Patent No. RE 37,721 (the "RE '721" patent)[8] and U.S. Patent No. 5,846,966 (the "'966" patent). The RE '721 patent purportedly covered Zetia and expired on April 25, 2017 (including pediatric exclusivity). Merck also asserted the RE '721 patent to protect its Zetia monopoly. The '966 patent purportedly covered the combination of Zetia and a statin and expired on March 21, 2014 (including pediatric exclusivity).

[8] RE '721 was reissued on June 14, 2011 as RE 42,461.

DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. Merck Improperly Seeks and Obtains at Least the '115 and RE '721 Patents.

62. In the 1990s, Schering began prosecuting a patent family that included U.S. Patent No. 5,767,115 (the "'115" patent). Schering pursued these prosecutions into the 2000s on behalf of Merck and MSP Singapore, securing reissue by the USPTO twice to correct supposed "mistakes" in the patents — first, the RE '721 patent, and then U.S. Reissue Patent No. RE 42,461 (the "RE '461" patent).[9] This family disclosed the ezetimibe molecule among what one court described as "a genus of approximately a quintillion beta-lactams that include hydroxy-substituted azetid[in]ones."

63. In prosecuting this patent family, Schering, Merck, and MSP Singapore bore a duty of disclosure to the USPTO. Under 37 C.F.R. § 1.56, each individual substantively involved with the filing and prosecution of a patent application has a duty to disclose to the USPTO "all information known to that individual to be material to patentability."

64. However, Schering, Merck, and MSP Singapore did not comply with their duty of disclosure. At least as of the filing of the patent application that led to the '115 patent, Schering was conducting research on the metabolization of a compound it dubbed "SCH48461." In lab experiments, Schering scientists, including inventors named on the '115 patent family, identified SCH48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH58235 — ezetimibe. To create SCH58235, Schering scientists used routine laboratory techniques to add fluorine to the two phenyl rings, in order to lessen the likelihood of hydroxylation (and thereby keep the compound in the body longer). The use of halogens to

[9] All references to actions taken by Schering, Schering-Plough, or Merck related to the development and prosecution of patents or initiation of patent infringement actions related to Zetia and Vytorin were taken as part of their joint venture and intended to secure and protect Merck's monopoly in the Zetia and Vytorin markets.

block sites of metabolism was then well known. Schering's research pre-dating the alleged inventions claimed in the '115 patent family was described in numerous articles published before and during the prosecution of the '115 patent family, however, Schering, Merck, and MSP did not disclose those publications until years later, after agreeing to withdraw several patent claims and acknowledging that, "[a]t least claim 1 of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 . . . ."

65. Schering had disclosed SCH48461 in an earlier application, application number PCT/US92/05972, published February 4, 1993 as International Publication No. WO 93/02048. And although Schering disclosed the existence of that publication to the USPTO in connection with the prosecution of the '115 patent family, neither Schering, Merck nor MSP explained what it disclosed to persons skilled in the art about the inventions claimed in the '115 patent family, nor did they disclose the metabolization studies until the prosecution of the application that matured into RE '461 patent (and only then after Glenmark had raised the issues in litigation).

66. Schering, Merck, and MSP's failure to disclose the information of the metabolization of SCH48461 was a breach of their disclosure obligations during prosecution of the '115 and RE '721 patents. Consequently, Schering was able to obtain patent claims that covered the inherent metabolites of SCH48461, along with metabolite-like analogues — *i.e.*, patent claims that impermissibly claimed naturally occurring compounds. And Schering, Merck, and MSP continued to prosecute those claims before the USPTO despite knowledge of the metabolization studies.

B. Merck Improperly Lists Patents for Zetia in the Orange Book.

67. When Merck was seeking approval of Zetia, it had to inform the FDA of any issued patents that covered the product so that they could be listed in the Orange Book. Listing such patents in the Orange Book allowed generic pharmaceutical companies to assess whether to challenge infringement and/or validity of the patents knowing that, if they prevailed in such a challenge, there would be no more patent barriers to entry of a generic version of Zetia.

68. For a patent to cover a product, the product must meet all the elements of at least one "claim" in the patent. A "claim" is the portion of the patent that defines, as a legal matter, the scope of the patent owner's right to exclude others from using the patented invention. By then end of 2004, Merck had listed two patents in the Orange Book.

69. One of the patents that Merck listed in the Orange Book, U.S. Patent No. 5,846,966 (the "'966 patent") claims a product that combines ezetimibe (Zetia) and a statin in one tablet. But, Zetia does not contain a statin, so Merck listed the '966 patent knowing that it did not cover Zetia.

70. Merck also improperly asserted the '966 patent against some generic pharmaceutical companies seeking generic approval for Zetia.

71. The other patent that Merck listed in the Orange Book was the RE '721 patent. Although RE '721 may purport to cover Zetia, Merck improperly asserted it against generic companies. The RE '721 patent was listed by Merck in the Orange Book for Vytorin as well.

72. At the time Merck listed the RE '721 in the Orange Book for Zetia, Merck knew or should have known that the patent was invalid in view of the prior art and/or unenforceable due to its own inequitable conduct in procuring the patent from the USPTO — the Merck inventors and/or the attorneys who prosecuted the patent application withheld material prior art

from the patent examiner and failed to identify the true inventors, and did so with the specific intent to deceive the patent examiner into issuing a patent on an alleged "invention" that Merck knew was unpatentable in view of its earlier work. In addition, Merck knew or should have known at the time it filed the patent application that the alleged invention was invalid due to due to double patenting, anticipation, obviousness, and/or lack of enablement.

C. Merck Improperly Obtains an Additional Patent Covering Zetia and Lists it in the Orange Book.

73. After Merck filed its NDA, but before the NDA was approved, Merck sought to extend its patent protection for Zetia and filed several patent applications in 2001 and 2002.

74. On April 18, 2006, Merck's U.S. Patent Application No. 10/136,968 issued as U.S. Patent No. 7,030,106 (the "'106" patent), titled "Sterol absorption inhibitor compositions." The patent names inventor Wing-Kee Philip Cho of Princeton, N.J., and lists the original assignee as Schering. The '106 patent includes two claims.

75. The '106 patent does not claim priority to the RE '721 patent or any members of the RE '721 patent family. Consequently, the RE '721 patent constituted prior art to the '106 patent.

76. Merck listed the '106 patent in the Orange Book for Zetia. There, the '106 patent is identified as having an expiration date of January 25, 2022, which was purportedly extended to July 25, 2022 based on a pediatric extension.

77. The Field of the Invention of the '106 patent states: "The present invention relates to compositions and therapeutic combinations comprising peroxisome proliferator activated receptor (PPAR) activator(s) ***and*** certain sterol absorption inhibitor(s) for treating vascular and lipidemic conditions such as are associated with atherosclerosis, hypercholesterolemia and other vascular conditions in mammals" (emphasis added).

78. The claims of the '106 patent do not refer to combination use. The claims purport to cover pharmaceutical compositions that include ezetimibe along with conventional ingredients. Accordingly, at least the RE '721 patent renders this patent invalid. At the time Merck caused the '106 patent to be listed in the Orange Book for Zetia, Merck knew that the '106 patent was invalid in view of at least the RE '721 patent.

D. Merck Receives New Regulatory Exclusivities.

79. The FDA granted Merck a five-year new chemical entity exclusivity ("NCE") for Zetia.

80. Thereafter, Merck applied for an additional regulatory exclusivity for Zetia for pediatric use. The FDA granted the pediatric exclusivity, which extended the term the of the RE '721 patent by six months.

E. Glenmark Files the First ANDA for Generic Zetia, and Merck Files a Baseless Lawsuit Against Glenmark.

81. October 25, 2006 was the first day that any generic company could file an ANDA. On that date, Glenmark filed ANDA No. 78-560 on Zetia, which included a Paragraph IV certification that asserted the patents listed in the Orange Book for Zetia — including the RE '721 patent, the '966 combination-with-statins patent, and the '106 patent — were invalid, unenforceable, and/or not infringed. However, because of Merck's regulatory exclusivity, the FDA was legally prohibited from approving Glenmark's ANDA for another year.

82. On March 22, 2007, Schering (as patent assignee) and MSP Singapore (as exclusive licensee of the patent) sued Glenmark in the U.S. District Court for the District of New Jersey alleging that Glenmark's ANDA infringed the RE '721 patent.[10] Under the Hatch-

[10] Schering was also a plaintiff in this and other affirmative patent actions related to Zetia and Vytorin. In filing these lawsuits with Merck, Schering aided Merck's efforts to maintain its

Waxman Act, Merck was required to assert all valid and enforceable patents that it reasonably believed would be infringed by Glenmark's proposed generic version of Zetia, but Merck did not claim infringement of the '966 patent or the '106 patent. Thus, Merck effectively admitted that the '966 and '106 patents were invalid, unenforceable, and/or did not cover Zetia. Under Hatch-Waxman, Schering and MSP Singapore's filing of the infringement action — irrespective of their likelihood of success — triggered a 30-month stay, running from the date Glenmark notified plaintiffs of its Paragraph IV certification. This stay prevented the FDA from granting final approval of Glenmark's ANDA until the earlier of (i) the expiration of the 30-month stay, or (ii) entry of a final judgment that the RE '721 patent was invalid, unenforceable, and/or not infringed.

83. On May 23, 2007, Glenmark answered Merck's complaint, asserting both affirmative defenses and counterclaims based on the invalidity and unenforceability of the RE '721 patent. In particular, Glenmark sought a declaratory judgment that the RE '721 patent was invalid because of double patenting, anticipation, obviousness, lack of enablement, and failure to identify the correct inventor. Glenmark also asserted that the patent was unenforceable due to inequitable conduct, including the failure to disclose material prior art to the USPTO with a specific intent to deceive the patent examiner. Because this is a fraud-based affirmative defense, it was pleaded with particularity, thereby putting plaintiffs on notice that the RE '721 patent was unenforceable (though Merck knew or should have known that already).

84. On March 10, 2008, Glenmark filed a First Amended Answer and Counterclaims. According to Glenmark, it amended its answer "to correct and supplement factual allegations for the fourth affirmative defense plead in its answer" and "to add two affirmative defenses and two

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monopolies on Zetia and Vytorin. As the other member of the joint venture, Schering had a vested economic interest in Merck's ability to maintain its monopolies over of these drugs.

corresponding counterclaims based on plaintiffs' conduct in obtaining a patent term extension for the patent-in-suit," among other things.

85. The Fourth Affirmative Defense of Glenmark's amended answer alleged that RE '721 "is unenforceable due to Schering's inequitable conduct and violation of the PTO Duty of Disclosure under [37 C.F.R. § 1.56]." The Sixth and Seventh Affirmative Defenses regard a patent term extension ("PTE") proceeding for RE '721, alleging, respectively, invalidity due to a failure to comply with the Patent Statute, and unenforceability due to Schering's "inequitable conduct and violation of the PTO Duty of Disclosure under [37 C.F.R. § 1.765]."

86. Glenmark alleged that, on information and belief, on July 21, 1992, Schering filed International Patent Application No. PCT/US92/05972 titled "Substituted Beta-Lactam Compounds Useful as Hypocholesterolemic Agents and Processes for the Preparation Thereof," which was published on February 4, 1993 as International Patent Publication No. WO 03/02048 ("PCT048"). PCT048 is prior art to the RE '721 patent and names at least two inventors in common with RE '721: Duane A. Burnett and John W. Clader.

87. According to Glenmark, PCT048 includes Example 9, which Schering subsequently referred to as "SCH48461." PCT048 also disclosed the administration of SCH48461 to mammals, including humans, to treat and prevent atherosclerosis, and experiments in which SCH48461 was administered to hamsters and exposed to rat microsomal proteins.

88. Glenmark further alleged that, on information and belief, Schering and other Schering individuals subject to a duty of disclosure continued to investigate SCH48461 after its discovery, including by performing experiments to isolate and characterize its metabolites. Glenmark alleged that, in view of at least these investigations, parties subject to the duty of disclosure knew or should have known that metabolites of SCH48461 were within the scope of

at least some claims of the RE '721 patent, and that these metabolites were inherently produced when administered to mammals or treated with rat microsomal proteins. Glenmark identified at least the following publications related to these allegations:

- "*In Vivo* Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH48461," by Margaret Van Heek, Constance F. France, Douglas S. Compton, Robbie L. McLeod, Nathan P. Yumibe, Kevin B. Alton, Edmund J. Sybertz, and Harry R. Davis, Jr., The Journal of Pharmacology and Experimental Therapeutics (Volume 283, No. 1) (Oct. 1997), at pages 157-163 ("Van Heek Publication").

- "Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors," by John W. Clader, Current Topics in Medicinal Chemistry (Volume 5, Number 3) (Apr. 2005), at pages 243-256.

- "Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible in vivo Mechanism of Action for their Inhibition of Cholesterol Absorption," by Margaret Van Heek, Douglas S. Compton, Constance F. France, Robert L. McLeod, Nathan P. Yumibe, Kevin B. Alton, and Harry R. Davis, Jr., XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

- "The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA Reductase Inhibitors," by Harry R. Davis, Jr., Margaret van Heek, Robert W. Watkins, Stuart B. Rosenblum, Douglas S. Compton, Lizbeth M. Hoos, Daniel G. McGregor, Katherine Pula, and Edmund J. Sybertz, XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

- "Discovery of SCH 58235. A Potent Orally Active Inhibitor of Cholesterol Absorption," Stuart B. Rosenblum, Tram N. T. Huynh, Harry R. Davis, Jr., Nathan P. Yumibe, John W. Clader, Adriano Afonso and Duane A. Burnett, XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

- "Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079 and Analog of the Potent Cholesterol Absorption

> Inhibitor (-) SCH 48461," by Sundeep Dugar, Nathan P. Yumibe, John W. Clader, Monica Vizziano, Keith Huie, Margaret Van Heek, Douglas S. Compton, and Harry R. Davis, Jr., Bioorganic & Medicinal Chemistry Letters, which was published in the November 1996 issue (Volume 6, No. 11), at pages 1271-1274.[11]

89. Glenmark alleged that parties subject to the duty of disclosure under 37 C.F.R. § 1.56 at least in regard to the prosecutions of: (1) the application that issued as the '115 patent, and (2) the application that issued as RE '721, breached that duty by not disclosing "all information known … to be material to patentability," including at least some or all of the above-listed publications, knowledge regarding the metabolites of SCH48461, the inherent anticipation of certain claims, and other material knowledge.

90. Glenmark alleged that parties subject to the duty of disclosure under 37 C.F.R. § 1.765 at least in regard to the Patent Term Extension proceeding for RE '721 breached that duty by not disclosing "material information adverse to a determination of entitlement to the extension sought," including at least some or all of the above-listed publications, knowledge regarding the metabolites of SCH48461, the inherent anticipation of certain claims, and other material knowledge.

91. With full knowledge of these well-founded defenses, the plaintiffs did not dismiss their litigation against Glenmark. Rather, they (along with Schering-Plough) continued to prosecute their claims against Glenmark.

92. While the Glenmark litigation was ongoing, on April 24, 2009, the FDA tentatively approved Glenmark's ANDA for Zetia. The FDA provided this approval within the time allotted by statute, which secured Glenmark's first-filer status for 180-day exclusivity. At

[11] Rather than repeat the details of Glenmark's discussion of these publications here, this pleading incorporates by reference ¶¶ 30-171 of Glenmark's First Amended Answer and Counterclaims (*Schering Corp. v. Glenmark Pharm., Inc., USA*, No. 07-cv-01334 (D.N.J. Mar. 10, 2008) (ECF No. 54), attached as Exhibit A.

the time Glenmark received tentative approval, the 30-month stay prevented it from launching its generic.

93. As a result, the claim that Glenmark had infringed the RE '721 patent was the only thing standing between Glenmark and approval of its ANDA.

94. Less than four months after the FDA tentatively approved Glenmark's ANDA for Zetia, Vijay Soni, Glenmark's lead negotiator at the time, exchanged email messages with Glenmark executives, Terrance Coughlin and Glenn Saldanha, which show that Glenmark knew the RE '721 patent was relevant, not only to Zetia, but also Vytorin. In the email dated August 5, 2009, Mr. Soni summarizes key points from a meeting with Henry Hadad, Schering Plough's general counsel, discussing settlement terms between the parties. As part of this summary, Mr. Soni notes that "[w]hile I did bring the matter of near future and also reminded [Mr. Hadad] of the fact that +ve [sic] court decision in favor of Glenmark will impact Vytorin product." Glenmark and Merck knew that invalidation and/or a determination of unenforceability of the RE '721 patent in the pending patent litigation would affect both Zetia and Vytorin.

95. On May 10, 2010, two days before trial was set to begin, the plaintiffs and Glenmark entered into an agreement to settle their litigation and unlawfully allocate the market for ezetimibe. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unrevealed caveats, Glenmark would not enter the market with its generic Zetia product until December 12, 2016.

96. The settlement agreement ensured that the RE '721 patent would not be invalidated and/or rendered unenforceable by the Glenmark patent litigation and could be used to protect both Zetia and Vytorin from generic competition.

F. Merck Admits that Its Lawsuit Against Glenmark Had No Merit.

97. On June 9, 2010, within a month of its settlement with Glenmark, Schering applied to the USPTO for reissuance of the RE '721 patent because it was wholly or partially invalid and unenforceable for at least some of the reasons Glenmark had alleged in its May 23, 2007 and March 10, 2008 pleadings. Schering had to submit a sworn declaration to the USPTO admitting that the patent was wholly or partially invalid and unenforceable for the patent to be re-issued. Mark Russell, legal director of patents for Schering Corporation, was that declarant. In his declaration, he attested to an error in the patent, and conceded that Glenmark's inherent anticipation argument was correct:

- "I have reviewed and understand the content of the above identified specification, including the claims . . . ."
- "I verily believe ***the original patent to be wholly or partly inoperative or invalid***, for the reasons described below . . . by reason of the patentee claiming more than he had the right to claim in the patent."
- "At least claim 1 of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 . . . ."
- "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed."

98. In Schering's preliminary remarks, attorneys Carl A. Morales and James F. Haley, Jr., of Ropes and Gray LLP, attorneys/agents for reissue applicants, made similar statements about inherent anticipation and invalidity being the basis for seeking reissue, and proposed amendments to the claims that ostensibly addressed these problems, namely cancelling claims 1-2 and 4-6 and amending claims 3 and 7-9.

99. During this proceeding, Schering finally disclosed the above-listed publications along with fourteen pages of additional references to the USPTO.[12] However, that disclosure could not, as a legal matter, "cure" Merck's inequitable conduct in withholding that information from the patent examiner in the first place, with an intent to deceive the patent examiner into issuing first the '115 patent, and then later the RE '721 patent.

100. On June 14, 2011, the RE '721 patent was reissued as the RE '461 patent. The RE '461 patent, as reissued, included only claims 8 through 13, and parts of claims 3 and 7, of the RE '721 patent. By requesting and receiving this second reissue, Merck attempted to insulate itself from other ANDA filers for Zetia using the dispositive defenses asserted by Glenmark. However, the law is clear that a party who secured a patent through inequitable conduct cannot expunge the inequitable conduct by "coming clean" and disclosing the previously withheld information in a later, related patent application. Not only is the original patent unenforceable, but so too are all later-issued patents in that same patent family.

G. Prior to the Settlement and Reissue, Par Becomes Glenmark's Partner in Generic Zetia, and Approves the Illegal Settlement Agreement.

101. On April 30, 2010, Glenmark and Par entered into the Distribution Agreement, whereby Glenmark designated Par to act as its exclusive distributor to market, distribute, and sell Glenmark's generic Zetia in the United States. In exchange for, among other things, an upfront payment to Glenmark and an agreement to share net profits, Glenmark granted Par the exclusive right to distribute its generic Zetia in the United States.

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[12] Publications, including at least those identified by Glenmark, Mylan, and other litigants, further show RE '721 was invalid based on anticipation and/or obviousness. For example, the Van Heek Publication demonstrates that ezetimibe resulted from minor modification of a metabolite of SCH48461: "A benzylic hydroxyl group was added to SCH53695 [a metabolite of SCH48461] and several of the sites that were readily metabolized in SCH48461 were blocked with fluorines resulting in SCH58235 [ezetimibe]."

102. Pursuant to the terms of the Distribution Agreement, Glenmark provided Par "all documents or materials in its possession or control" relating to the ANDA litigation between Merck and Glenmark. The Agreement required Par and Glenmark to "jointly" make "all material decisions" in the Merck/Glenmark patent infringement litigation or any other litigation involving generic Zetia. Specifically, section 9.2.2 of the Distribution Agreement, entitled "Decisions," provided:

> 9.2.2 Decisions. Glenmark shall keep Par reasonably informed regarding material developments with respect to any Litigation. Glenmark shall continue to control the defense of the Litigation, except that all material decisions with respect to the Litigation shall be made jointly by Glenmark and Par; provided, however, that if the Parties fail to promptly agree upon a course of action, Glenmark's decision shall control any Litigation as well as any settlements thereof. Glenmark and Par, to the extent necessary to protect and preserve the attorney-client privilege between Glenmark and its counsel, shall enter into a common interest and/or joint defense agreement.

103. Under the terms of the Distribution Agreement, Glenmark could not settle its lawsuit with Merck without Par's "written consent." And, if any such settlement were to occur, Glenmark was required to share any proceeds with Par. Pursuant to this provision, Par gave its written consent to the unlawful reverse payment agreement between Merck and Glenmark.

104. The Distribution Agreement also required Par to consult with Glenmark regarding marketing, pricing, and distribution decisions, and explicitly established a Steering Committee comprised of "an equal number of duly qualified representatives of Par and Glenmark . . . with the necessary authority to deal with and make decisions concerning the matters within the Steering Committee's authority." The Steering Committee's responsibilities included:

- "advise on the overall strategy for the marketing of the Product [generic Zetia]";
- "review and advise on the marketing plan";
- "monitor the activities and performance of Par related to the marketing plan";

- "review and advise on decisions in connection with the marketing plan";
- "review and advise on major amendments to the marketing plans, including without limitation, with respect to timelines and budgets";
- "discuss pre-Launch marketing plans and strategies (including the estimated Launch Date)"; and
- "review and advise on life cycle management plans for the Product [generic Zetia] after the Product has been launched or has been actively planned for Launch."

105. The Distribution Agreement required Glenmark and Par to establish the Steering Committee within 30 days of the Agreement's execution and to meet a minimum of twice a year. It also provided that the Steering Committee would be chaired by a Glenmark representative prior to "pre-Launch commercialization planning" but thereafter by a representative of Par. Under the Agreement, Par became Glenmark's partner in the profits made from the sale of Glenmark's generic Zetia in the United States, as well as the Merck/Glenmark ANDA litigation, any settlement of that litigation, and any proceeds or benefits of such a settlement.

106. Par knowingly and voluntarily agreed to the terms of the unlawful settlement and authorized its execution by Glenmark. By operation of the Distribution Agreement, Par and Glenmark were partners in the distribution of Glenmark's generic Zetia; both conspired with Merck to delay the entry of generic Zetia and to allocate the market for generic Zetia in the United States.

107. Par performed under the Distribution Agreement by consenting to the unlawful reverse payment agreement between Merck and Glenmark, by distributing Glenmark's generic Zetia in the United States, and by furthering the purposes of the unlawful conspiracy. Par benefited from the conspiracy because the profits it retained from the sale of Glenmark's generic Zetia were higher than they otherwise would have been as a result of the delay-induced higher drug prices and the absence of competition from a Merck authorized generic.

H. The Confidential Merck-Glenmark Settlement Agreement Includes an Illegal Reverse Payment.

108. The Merck-Glenmark settlement agreement was not docketed in the court record, and the parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement. Nor have the full terms of that agreement been made public.

109. Because Merck and Glenmark kept the terms of their unlawful agreement confidential, the existence of the No-AG agreement could not have been discovered until Glenmark launched its generic in 2016, and Merck failed to launch a competing AG.

110. Since the time Glenmark launched its generic, certain terms of the reverse payment agreement have become public. The reverse payment agreement confirms that, as a quid pro quo for Glenmark's agreement to drop its patent challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark's 180-day exclusivity period. Under sections 5.2 and 5.4 of the reverse payment agreement, Glenmark agreed not to launch generic Zetia until December 12, 2016 (or earlier under certain limited circumstances that never occurred). Under section 5.3 of the unlawful reverse payment agreement, Merck agreed not to launch an authorized generic in competition with Glenmark "[d]uring any period of exclusivity to which Glenmark is entitled under 21 U.S.C. § 355(j)(5)(B)(iv) [180-day exclusivity], and through the expiration of [Merck's] rights under the RE '721 Patent and Ezetimibe Pediatric Exclusivity." Accordingly, Glenmark was permitted to launch generic Zetia on December 12, 2016, Merck's rights under the RE '721 Patent (including pediatric exclusivity) expired on April 25, 2017, and Glenmark's 180-day exclusivity expired on June 10, 2017.

111. Merck's and Glenmark's internal documents reveal that both companies understood the reverse payment agreement to prohibit Merck's launch of an AG for some period of time after Glenmark's entry.

112. The No-AG agreement also can be inferred from the following facts:

- Merck previously admitted that marketing an AG is typically in its economic interest. For example, when referring to another blockbuster drug nearing the end of its exclusivity period, a Merck executive acknowledged that Merck's "authorized generic strategy" will "maximize the value of the franchise" after entry by generic competitors.

- Merck had a well-established history of launching AGs in the face of generic competition. Other branded drugs for which Merck or Schering have launched AG versions include: Blocadren, Clinoril, Cozaar, Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, Blocadren, K-Dur 10, K-Dur 20, and Lotrimin AF.

- Zetia was a blockbuster drug, with sales in the billions at the time a generic eventually launched in 2016. Absent Glenmark's reciprocal agreement to delay entering the market, launching an AG would have been in Merck's clear financial interest.

- When Glenmark launched its generic on December 12, 2016, it issued a press release describing its generic Zetia as "the first and only generic version" of Zetia in the United States.

- When Glenmark eventually launched generic Zetia in late 2016, Merck did not launch an AG during Glenmark 180-day exclusivity period. The absence of a Merck AG on the market in late 2016 and the first half of 2017 is strong evidence that Merck had a contractual agreement with Glenmark not to launch such a product. During this time period — the first six months of generic launch — Merck stood to earn millions of dollars from launching an AG.

- Before launching its generic product, Glenmark reported to its shareholders in May 2017 that it expected to garner more than 58% of the combined brand and generic sales, which it in fact achieved within the first six months. In the absence of a No-AG agreement, a typical generic pharmaceutical company would realistically expect to take a smaller share of the market (25-43%) due to competition from an AG.

113. The No-AG agreement was a payment from Merck to Glenmark worth substantially more than what Glenmark could have earned if it had prevailed in the patent

litigation filed by Merck and come to market with generic Zetia in 2011 (or later) and had to compete with Merck's AG. Further, Glenmark could not have obtained a No-AG agreement even had it won the patent infringement litigation. By delaying its generic entry for more than five years, and thereby obtaining a No-AG agreement from Merck, Glenmark was ensured six months of exclusive generic sales, free from competition from Merck's AG or any other generic competitors.

114. For Merck, the benefits of the No-AG agreement were enormous, because it secured at least an additional five years of monopoly profits. The size of Merck's payment is strong evidence of Merck's belief that it would lose the patent litigation.

115. Absent the reverse payment agreement, generic entry would likely have occurred by at least as early as December 6, 2011, when Merck's regulatory exclusivity ended. By then, Glenmark would have resolved the RE '721 patent infringement claims by either winning at trial or settling on competitive terms (without a reverse payment). Merck has never accused Glenmark of infringing any other Orange Book-listed patents covering Zetia.

116. By December 6, 2011, no impediments existed to the prompt approval and launch of generic Zetia other than Merck's assertion of infringement of the RE '721 patent.

- The FDA had already tentatively approved Glenmark's ANDA, demonstrating that Glenmark had effectively met all preconditions for final FDA approval other than the 30-month stay triggered by Merck's enforcement of the RE '721 patent against Glenmark.
- No other patents held by Merck could forestall generic entry. The '966 patent had claims only to combination products (generic Zetia is not a combination product), and Merck never enforced the '966 patent against Glenmark. The '106 and '058 sterol non-absorption patents were obvious in light of the RE '721 disclosures, and Merck never enforced those patents against Glenmark. The '365 patent was limited to the narrow processes set out in that patent, and Merck never enforced the '365 patent against Glenmark.

- Merck had no other exclusivity rights after December 5, 2011. Merck's new chemical exclusivity expired in 2007. Two other exclusivities — an indication exclusivity I-493 and a pediatric exclusivity M-54 — were capable of being carved out of any generic label and had expired by December 5, 2011.

I. Absent the Illegal Settlement Agreement and Other Improper Conduct, Generic Competition Would Have Begun Much Earlier.

117. In the absence of Merck's inequitable conduct before the USPTO and the illegal reverse payment agreement to settle the Glenmark litigation, generic entry would have occurred much sooner than it did. Such earlier entry would have occurred in one of four alternative ways.

118. First, Merck may never have brought its infringement lawsuit involving the RE '721 patent or even obtained the RE '721 patent. As Merck later effectively admitted, there was no legal basis for such a lawsuit, and Merck intentionally withheld prior art during the prosecution of the RE '721 patent that would have led the USPTO to deny Merck's patent application. Absent Merck's unlawful conduct, Glenmark could have entered the market as soon as its ANDA was approved and Merck's regulatory exclusivity expired.

119. Second, even assuming the lawsuit had been brought, it would have been dismissed by Merck as meritless as soon as Glenmark asserted its defenses, causing Merck to conclude (as it later admitted) that its infringement claim was without merit. And Glenmark's date for entry as a generic competitor would have been in line with the absence of any defense to such entry by Merck. Either outright dismissal of the litigation, or an arms-length settlement between economically rational, law-abiding companies would have led to an agreed entry date soon after Glenmark's defenses to the lawsuit were filed.

120. Third, Glenmark and Merck would have negotiated an alternative settlement agreement that did not include a reverse payment. An alternative settlement would have resulted in Glenmark entering the market well before December 2016.

121. Fourth, assuming there was no settlement, Glenmark would have won the trial scheduled to start in May 2010. In that trial, a finder of fact would have concluded, as Merck later admitted, that its lawsuit had no merit. More generally, the fact finder would have concluded that Merck failed to prove that Glenmark infringed a valid, enforceable patent for one or more of the reasons Glenmark alleged, including at least the following reasons:

- Merck (through the inventors, agents, and others with a duty of disclosure to the USPTO under 37 C.F.R. § 1.56) committed inequitable conduct by intentionally and deceptively hiding the fact that the RE '721 patent claimed compounds that were naturally occurring metabolites of SCH 48461 (and therefore inherently anticipated by its earlier disclosure in PCT '048), which would render the entire RE '721 patent invalid or unenforceable;

- Merck (through the inventors, agents, and others with a duty of disclosure to the USPTO under 37 C.F.R. § 1.56) committed inequitable conduct by intentionally and deceptively failing to properly name the correct inventors;

- Regardless of whether Merck committed inequitable conduct, the claims of the RE '721 patent were invalid for inherent anticipation; and

- Claims of the RE '721 patent were invalid for obviousness-type double patenting.

122. Having gone to trial and won, Glenmark would have launched generic Zetia soon after the district court ruled in its favor and the expiration of any other, lawful exclusivity (such as any additional regulatory exclusivities).

123. Without Merck's reverse payment to Glenmark, several additional generics would have come to market after Glenmark's 180-day exclusivity ended. And in the absence of the unlawful agreement, Merck would have launched its AG version of Zetia at or around the same time that Glenmark launched its generic.

124. For example, if a generic product had entered the market in December 2011, Merck would have lost at least 80% of its sales of branded Zetia. By forestalling generic entry,

Merck kept those sales at higher than competitive prices for as many as five years. Therefore, the benefit to Merck of the reverse payment agreement was in the billions of dollars.

125. But for the illegal reverse payment agreement, Glenmark would have launched its generic product at least as early as 2011 in competition with Merck's AG. Instead, as a result of the reverse payment agreement, Glenmark launched in 2016 in a market with no other generic competitors.

126. Discovery will reveal how Glenmark subjectively valued the benefits it obtained from the reverse payment agreement, but one can reasonably estimate the value to Glenmark by comparing the profits it would likely have earned but for the reverse payment agreement ("but-for profits") to the profits it actually earned in 2016.

127. To estimate Glenmark's "but-for" profits, one can apply certain well-grounded assumptions to publicly known facts.

128. First, to estimate what Merck would likely have earned had it entered the market in 2011, one can start from the fact that Merck earned approximately $1.298 billion in branded Zetia sales that year. Based on empirical data on generic entry, one can reasonably assume that (a) the generic products (including an authorized generic) would have captured 80% of Zetia sales by discounting generic prices by as much as 50% off the brand price and (b) Glenmark would have captured half of all generic Zetia sales. This implies that Glenmark would have generated sales of $129.8 million during the six-month exclusivity period in 2011.

129. Second, to estimate what Glenmark actually earned in generic Zetia sales in 2016, one can start with the fact that branded Zetia prices increased by approximately 100% (taking into account higher prices and higher sales volumes) between 2011 and 2016 (annual U.S. sales of $2.6 billion), (b) Glenmark charged approximately 80% of the branded price during the 180-

day exclusivity period and (c) Glenmark captured 100% of generic sales during the exclusivity period. Applying these assumptions, Glenmark earned an estimated $832 million in 2016 during its period of exclusivity. The net value to Glenmark of the reverse payment agreement was therefore in excess of $700 million at the time of the agreement.

J. Merck Is Challenged by Additional Generic Manufacturers.

130. In or about April 2010, Mylan Pharmaceuticals, Inc. ("Mylan") became the second manufacturer to file a Paragraph IV certification for generic Zetia, which resulted in Merck filing a new case against Mylan on June 16, 2010. Merck initially alleged infringement of the RE '721 and '966 patents, but later withdrew its assertion of the '966 patent. In defense, Mylan raised many of the arguments initially raised by Glenmark. Ultimately, Merck filed an amended complaint substituting the RE '461 patent for the RE '721 patent, which made many of the defenses Glenmark asserted much more difficult for Mylan to establish. Mylan's ANDA for Zetia was tentatively approved by the FDA on August 7, 2013. But, Mylan could not enter the market until its case with Merck was over. Mylan eventually dropped nearly all of its defenses and only asserted an inequitable conduct defense based on misrepresenting inventorship of the RE '461 patent. It eventually lost on this defense at trial.

131. On July 21, 2010, while Merck's litigation with Mylan was still ongoing, Teva Pharmaceuticals ("Teva") notified Merck that Teva had filed for approval to make generic Zetia. Merck sued Teva on September 1, 2010. The parties settled on July 7, 2011. The settlement agreement prohibited Teva from launching generic Zetia before April 25, 2017.

132. In August 2012, Sandoz notified Merck that it had filed an ANDA for approval to market generic Zetia. On September 27, 2012, Merck sued Sandoz for infringement of the RE '461 patent. On September 5, 2013, before the pleadings were closed and before any further

proceedings or any substantive rulings in the case, Merck and Sandoz settled all issues in the patent infringement litigation. According to the consent judgment entered, under the terms of the settlement, Sandoz was precluded from launching its generic Zetia before April 25, 2017.

K. Glenmark Launches a Generic Form of Zetia — Merck Does Not.

133. Glenmark's ANDA 78-560 received final approval from the FDA on June 26, 2015. In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180-days of market exclusivity upon launch.

134. On December 12, 2016, Glenmark launched its generic Zetia and issued a press release describing its product as "the first and only generic version" of Zetia in the United States.

135. From December 12, 2016, through June 12, 2017, Glenmark's product was the only generic version of Zetia sold in the U.S. market.

136. Merck refrained from launching an AG version of Zetia during Glenmark's 180-day exclusivity period. It did so pursuant to the No-AG provision in the parties' unlawful agreement.

L. 180 Days Later, Five More Generics Launch.

137. On or about June 12, 2017 — the day Glenmark's 180-day exclusivity period expired — the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).

138. Five of these manufacturers — Teva, Sandoz, Amneal, Apotex, and Ohm Laboratories — launched a generic Zetia product in June 2017, shortly after receiving FDA approval. Zydus launched its generic Zetia product two months later, in August 2017. The

seventh manufacturer, Watson Laboratories, sold its generic drug business to Teva before June 2017 and, thus, did not launch a generic Zetia product.

139. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017. Aurobindo launched its generic Zetia product later that month. An additional ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017.

M. Merck Used these Same Zetia Patents to Improperly Prevent Generic Competition to Vytorin.

140. For several years, Merck sold both Zetia and Zocor (simvastatin), branded-drugs that could be used individually or as complements to each other. But, Zocor's patent and regulatory exclusivity was set to expire in 2006 — ending Merck's monopoly over the dynamic Zocor and Zetia combination therapy. Further compounding the problem, at the time, the company was facing "serious challenges" on several fronts and suffering significant financial losses.[13]

141. In response, Merck, through its partnership with Schering-Plough, decided to combine Zocor and Zetia into one tablet, effectively reestablishing a monopoly over Zocor using the patent protection that Zetia was still afforded. In 2003, MSP Singapore filed NDA N021687 for Vytorin, a product combining known doses of Zocor and Zetia. The NDA was approved July 23, 2004, and received the same new chemical entity exclusivity as Zetia, granting it exclusivity until October 25, 2007.

142. Although Merck marketed Vytorin as a "unique dual-inhibition therapy," the drug is nothing more than combining two known compounds — Zetia and Zocor — in an entirely

[13] Schering-Plough, *Schering-Plough Reports Financial Results for 2004 First Quarter* (April 22, 2004), available at https://www.sec.gov/Archives/edgar/data/310158/000095012304004939/y96529exv99w1.htm.

predictable way.[14] For example, when taken separately, Zocor is prescribed in doses of 10 mg, 20 mg, 40 mg, or 80 mg, while Zetia is prescribed exclusively in 10 mg doses. Vytorin is available in four doses: 10 mg Zetia with 10 mg Zocor; 10 mg Zetia with 20 mg Zocor; 10 mg Zetia with 40 mg Zocor; and 10 mg Zetia with 80 mg Zocor.

143. Merck's plan worked. Like Zetia and Zocor, Vytorin became a blockbuster drug and generated billions of dollars in sales for Merck. In fiscal years 2014 to 2016, Merck's combined global sales for Zetia and Vytorin were $4.17 billion ($2.65 billion Zetia, $1.52 billion Vytorin), $3.78 billion ($2.526 billion Zetia, $1.25 billion Vytorin), and $3.7 billion ($2.56 billion Zetia, $1.14 billion Vytorin), respectively. In the United States, sales for Zetia and Vytorin were $1.6 billion and $473 million, respectively, for fiscal year 2016.

144. As of the end of 2013, two patents were listed in the Orange Book for Vytorin (excluding RE '721, which, by then, had been superseded by RE '461). Merck listed the '966 patent with a September 21, 2013 expiration date, and Merck listed RE '461 with an October 25, 2016 expiration date. The Orange Book indicated that Vytorin enjoyed a 6-month pediatric exclusivity extension to these expiration dates. Thus, after at least March 21, 2014, Merck's exclusivity for Vytorin was based solely on patent RE '461.

N. The Generic Manufacturers Challenge Vytorin.

145. Mylan was the first generic competitor to file an ANDA for Vytorin. On December 16, 2009, Merck sued Mylan on the RE '721 patent and the '966 patent (which it later dropped). In response, Mylan raised all of the same defenses that Glenmark raised in its Zetia litigation, including the same inequitable conduct defenses. As discussed above, Merck effectively admitted that all of these defenses were meritorious when it sought the reissue of the

[14] *Id.*

RE '721 patent, which ultimately issued as the RE '461 patent on June 14, 2011. Nonetheless, Merck continued the litigation. Mylan took substantial discovery on its defenses. Merck requested summary judgment on the issue that it had not committed inequitable conduct by failing to disclose material information to the USPTO during prosecution.

146. On August 22, 2011, the court denied Merck's motion for summary judgment on Mylan's defense of inequitable conduct for failure to disclose prior art to the USPTO, holding that "Mylan has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art," and that "a deliberate decision to withhold that information could . . . be reasonably inferred from the evidence already presented." The court also noted: "Schering does not appear to dispute that it had knowledge of the metabolite information during prosecution." Accordingly, the court denied the motion because the credibility of Merck's patent prosecution counsel needed to be assessed by the fact finder, even though Mylan had established all of the legal elements to prove its defense.

O. Defendants Intended to and Did Harm Competition.

147. The purpose and effect of Defendants' conduct was to delay, foreclose, and/or severely limit generic competition to brand-name Zetia and Vytorin. Merck's overarching scheme was specifically designed to delay and substantially diminish the sale of generic Zetia and to enable Merck to sell Zetia and Vytorin at inflated prices for years longer than it was entitled to do under the laws regulating generic drugs. Moreover, by engaging in this scheme with Merck, Glenmark did not simply delay its own sales of generic Zetia, but it blocked and delayed other potential competitors as well. Glenmark and Merck also knew the agreement would prevent earlier Vytorin generic entry.

148. Whereas only brand-name Zetia was available to purchasers and consumers before December 2016, and only brand-name Zetia and Glenmark's generic Zetia were available from December 2016 to June 2017, by July of 2017 there were six generics available on the market in addition to branded Zetia. By September of 2017 there were eight generics in addition to branded tablets.

149. Defendants' conduct delayed, prevented, and impeded the sale of, and competition from, generic Zetia in the United States, unlawfully enabling Merck to sell Zetia and Glenmark to sell generic Zetia at artificially inflated prices. This conduct was exclusionary and an unreasonable restraint on competition.

150. Absent Merck's, Schering-Plough's, and Schering's failure to disclose prior art to the PTO, the improper identification of patents for listing in the Orange Book, the companies' (and their respective subsidiaries') decision to initiate unsupported patent litigation claims against Glenmark, and to execute the No-AG agreement that illegally settled it, Glenmark would have entered the market far earlier with less expensive generic Zetia. Merck would have launched a competing AG at prices well below the branded price for Zetia and additional generics would have entered the market six months later and further driven down prices in competition with both Zetia and Vytorin.

151. As a result of Defendants' illegal conduct, Humana paid for Zetia and Vytorin at prices that were substantially greater than the prices it would have paid absent the illegal conduct alleged in this Complaint because: (a) it was deprived of an opportunity to purchase lower-priced generic Zetia instead of the brand-name Zetia and to purchase lower-priced generic Zetia and simvastatin instead of brand-name Vytorin, at earlier times; and (b) the prices of branded Zetia and branded Vytorin were artificially inflated by Defendants' illegal conduct. As a

consequence, Humana has sustained substantial losses and damage to its businesses and property in the form of overcharges paid for Zetia and Vytorin.

P. Effects on Interstate Commerce.

152. At all material times, Zetia and Vytorin, manufactured and sold by Merck, was shipped across state lines and sold outside its state of manufacture. Merck and Glenmark directed the sale of Zetia, and its AB-rated generic equivalents, as well as Vytorin throughout the United States.

153. At all relevant times, Plaintiff was responsible for paying for Zetia, generic Zetia, and Vytorin obtained by members across the United States. As a result of Defendants' unlawful conduct, health plans such as Humana paid supracompetitive prices for Zetia and its generic equivalents, as well as Vytorin.

154. Defendants' unlawful activities, as described herein, affected the flow of interstate commerce and had direct, substantial and reasonably foreseeable effects upon such trade and commerce.

155. But for Defendants' anticompetitive conduct, Humana would have (1) purchased and/or paid for lower-priced generic Zetia, instead of higher-priced branded Zetia (including purchasing generic Zetia along with simvastatin instead of branded Vytorin), during the period when Glenmark delayed its entry to the market; (2) paid a lower price for Zetia during Glenmark's 180-day exclusivity period; and (3) paid lower prices for branded Zetia, as a result of the entry of generics at an earlier date, sooner.

156. Before generic Zetia became available, Merck consistently increased prices for Zetia. Generic entrants typically price their products at a discount to the then-prevailing price for the branded product. The first generic entrant generally prices at a modest discount to the

branded price. When more than one generic manufacturer enters the market, generic prices fall rapidly and those generic products capture most of the brand's sales volumes. This is known as the generic "cliff." That is what happened with Zetia once generic competition actually occurred, years later than it should have. Had generic entry occurred earlier, the first generic entrant would have discounted from a lower price point and competition would have rapidly driven prices down to competitive levels.

157. Due to Defendants anticompetitive conduct, the only substitutes for Vytorin were separate prescriptions for Zetia and simvastatin.

158. Had generic Zetia become available before generic Vytorin, Humana would have investigated the financial implications of mandating its members switch from branded Vytorin to generic ezetimibe and simvastatin and could have utilized mechanisms, such as formulary tier placement, to encourage and/or require members to substitute single-pill branded Vytorin for a two-pill regime of generic Zetia and simvastatin.

159. As a direct and proximate result of Defendants' conduct, Humana suffered significant losses and damages to its business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. Humana alleges that the anticompetitive effects of the conduct continued through at least 2019.

160. The economic harm that Defendants' conduct caused to Humana is measurable and quantifiable. Commonly used and well-accepted economic models can be used to measure both the existence and the amount of the supracompetitive charges paid by Humana.

MERCK'S MONOPOLY POWER

161. Before December 12, 2016, Merck had monopoly power in the market for Zetia because it had 100% market share of Zetia and possessed the power to exclude competition

and/or raise or maintain the price of Zetia at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

162. From December 12, 2016 to June 12, 2017, Merck and Glenmark combined had substantial market power for Zetia and its generic equivalent, because they shared 100% of the market and had the power to exclude competition and/or raise or maintain the price of ezetimibe at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. Before December 12, 2016, a small but significant, non-transitory increase to the price of branded Zetia did not cause such a significant loss of sales that the price increase was not profitable. From December 12, 2016 through the end of all exclusivity, a small but significant, non-transitory increase in the price of generic Zetia would not have caused a significant loss of sales.

163. Before April 26, 2017, Merck had monopoly power in the market for Vytorin because it had 100% market share of Vytorin and possessed the power to exclude competition and/or raise or maintain the price of Vytorin at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

164. Branded Zetia does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for hypercholesterolemia other than AB-rated generic versions of Zetia. That is, in the absence of AB-rated generics, a small but significant and non-transitory increase in the price of Zetia would not cause Merck to lose sufficient sales to other drugs to make the price increase unprofitable.

165. Branded Vytorin — comprised of branded Zetia and Zocor, a statin — also does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for hypercholesterolemia other than AB-rated generic

versions of Zetia and a statin or, once available, AB-rated Vytorin. That is, in the absence of AB-rated generics, a small but significant and non-transitory increase in the price of Vytorin would not cause Merck to lose sufficient sales to other drugs to make the price increase unprofitable.

166. The pharmacological profile and mechanism of action for Zetia is different from other cholesterol drugs, such as statins. Statins cannot be automatically substituted for Zetia by pharmacists, and are not economic substitutes for, nor reasonably interchangeable with, Zetia. As discussed above, approximately half of Zetia prescriptions were for statin-intolerant patients, and the remaining half were sold as complements to statins.

167. As a combination of Zetia and Zocor, Vytorin benefits from the unique pharmacological profile and mechanism of Zetia; and Vytorin is distinguishable from other cholesterol drugs, including those that combine statins with other therapies. The lack of reasonably interchangeable substitutes for Zetia is imputed to Vytorin.

168. Merck needed to control only branded Zetia and its AB-rated generic equivalents, and no other products, in order to maintain the prices of Zetia and Vytorin profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would prevent Merck from maintaining extremely high and profitable prices for Zetia and Vytorin without losing substantial sales.

169. During Glenmark's 180-day exclusion period, Merck sold branded Zetia and Vytorin, Glenmark sold generic Zetia at prices well in excess of marginal costs and in excess of the competitive price, and therefore, Merck and Glenmark enjoyed high profit margins.

170. Merck had, and exercised, the power to exclude generic competition to branded Zetia and Vytorin.

171. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Zetia and Vytorin from the forces of price competition.

172. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Defendants' ability to control the prices of Zetia, Vytorin, and generic Zetia, and/or to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Zetia would have entered the market at a much earlier date, at a substantial discount to branded Zetia, but for Defendants' anticompetitive conduct; (b) Merck's gross margins on Zetia and Vytorin (including the costs of ongoing research/development and marketing) at all relevant times was very high; and (c) Merck never lowered the prices of Zetia or Vytorin to the competitive level in response to the pricing of other brand or generic drugs.

173. To the extent that Humana is required to prove monopoly power circumstantially by first defining the relevant product market, Humana alleges two relevant product markets for antitrust purposes: Zetia and its AB-rated generic equivalents, and Vytorin and its AB-rated generic equivalents. The relevant geographic market is the United States.

ACCRUAL AND TOLLING

174. Each time that Humana paid an overcharge for branded or generic Zetia or Vytorin, a new cause of action accrued for that overcharge — i.e., each time payment was made at a price higher than would have been paid absent Defendants' unlawful conduct.

175. In addition, prior to the filing of this Complaint, Humana was an absent class member under numerous class action complaints filed in January 2018. Pursuant to the United States Supreme Court's decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538

(1974) and its progeny, the class action complaints tolled the applicable statute of limitations as to Humana's claims. Accordingly, Humana is entitled to recover overcharges on all purchases and/or payments made starting at least four years prior to the filing of those class cases, i.e., January 2014 and later.

176. In addition, Humana is entitled to recover damages on purchases made prior to January 2014 because Defendants fraudulently concealed their unlawful conduct, and Plaintiff did not and could not have discovered that conduct by the exercise of reasonable diligence prior to December 2016, thereby tolling the statute. Merck's payment to Glenmark in the form of a No-AG promise was not discoverable until after Glenmark launched its generic Zetia in December 2016, and Merck did not launch an AG. Merck and Glenmark had previously disclosed only cursory information about their reverse payment agreement.

177. Plaintiff's claims are tolled from December 11, 2020 to the date this Complaint is filed pursuant to a stipulation between Plaintiff and Defendants signed September 10, 2021.

178. Defendants' scheme was self-concealing, in that, by its nature and design, it was incapable of being detected. In addition, Defendants actively concealed their conspiracy to avoid detection.

179. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff by, among other things:

- Concealing from the USPTO information in their possession regarding metabolite studies of SCH48461 and inventorship despite a duty to disclose material information;
- Improperly listing patents in the Orange Book for Zetia and Vytorin, despite their invalidity, unenforceability, and/or inapplicability to those products;
- Asserting the RE '721 patent (and, later, RE '461) in litigation to exclude others from the market despite concealing material information from the USPTO;

- Concealing the fact of Merck's agreement not to launch a competing AG Zetia product in exchange for Glenmark/Par's agreement not to market its competing generic product until December 12, 2016;

- Concealing the fact that the purpose of the No-AG agreement was to provide compensation to Glenmark/Par in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark/Par's generic product; and

- Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

180. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the Defendants, Plaintiff had no knowledge of the conspiracy until December 2016 and could not have uncovered it before that date through the exercise of reasonable diligence, which Plaintiff exercised.

181. Plaintiff also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred.

CLAIMS FOR RELIEF

COUNT I:
Monopolization in Violation of Various State Antitrust Laws
(Against Merck)

182. Humana incorporates by reference the allegations in Paragraphs 1 through 181, above.

183. At all relevant times, Merck possessed monopoly power in the relevant market. Prior to their merger, Merck and Schering-Plough possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market through their joint venture. After the merger, Merck solely possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

184. As described throughout this Complaint, Merck knowingly and willfully engaged in anticompetitive conduct designed to unlawfully extend and maintain its monopoly power.[15]

185. By obtaining patents through inequitable conduct, improperly causing inapplicable, invalid and/or unenforceable patents to be listed in the Orange Book, bringing and maintaining unfounded patent litigation claims against Glenmark, and entering into a reverse payment agreement with Glenmark, Merck, with Schering-Plough's assistance, willfully and intentionally maintained, enhanced, and extended its monopoly power through restrictive and exclusionary conduct. Specifically, Merck and Schering-Plough intentionally withheld material prior art from the USPTO that would have barred issuance of the RE '721 patent, brought and maintained patent litigation that they later admitted was meritless, and then effectively paid Glenmark and Par hundreds of millions of dollars to delay the launch of Glenmark's generic Zetia product so that 100% of the Zetia market was allocated to Merck until December 12, 2016.

186. By extending its monopoly, Merck, with Schering-Plough's, Schering's, Par's, and Glenmark's assistance, was able to prevent and/or delay competition by at least 5 years and continue charging monopoly prices for Zetia and Vytorin without any significant loss of sales. If Glenmark, Par, and other manufacturers had entered the market, they would have fairly competed with Merck, and Humana would have paid dramatically lower prices for some or all ezetimibe products (and products containing ezetimibe), beginning at least as early as 2011.

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[15] For purposes of clarity, Plaintiff specifically alleges that Merck & Co., Inc. and its subsidiaries acted in concert with Schering-Plough and its subsidiaries at all times before their 2009 merger and continued acting in concert through the time the unlawful settlement agreement was signed with Glenmark. Indeed, Schering-Plough, Schering, Merck & Co., and MSP Singapore LLC (a subsidiary of Merck & Co., Inc.) sought and obtained the Zetia NDA. Schering-Plough and Schering prosecuted the RE '721 patent (and its family members) and conducted research on the metabolites of SCH48461, but did not disclose that research to the USPTO. And Schering and MSP Singapore LLC initiated the baseless patent actions against Mylan and Glenmark related to Zetia, and both companies are signatories to the settlement agreement with Glenmark that contains the No-AG Agreement.

187. Merck's conduct violated antitrust and competition statutes of all States and territories that may provide any relief for indirect purchasers/payors, including but not limited to each the following such laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of Zetia, Vytorin, and generic Zetia in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New York;

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Zetia, Vytorin and generic Zetia in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in West Virginia; and

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wisconsin.

188. Merck's conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

189. Merck's unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for the drugs at issue paid for, and/or dispensed in each State or territory.

190. Merck's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

191. During the relevant period, through either Merck itself or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

192. There was and is a gross and unconscionable disparity between the price that Humana paid for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Merck's illegal conduct.

193. As a direct and proximate result of Merck's violation of each of the foregoing laws, Humana has been harmed by paying artificially inflated, supracompetitive prices for Zetia, generic Zetia, and Vytorin dispensed to members throughout the United States, and Humana has suffered damages in an amount to be proven at trial.

COUNT II:
Conspiracy to Monopolize in Violation of Various State Antitrust Laws
(All Defendants)

194. Humana incorporates by reference the allegations in Paragraphs 1 through 193, above.

195. At all relevant times, Merck possessed monopoly power in the relevant market. Prior to their merger, Merck and Schering-Plough possessed the power to control prices in,

prevent prices from falling in, and exclude competitors from the relevant market through their joint venture. After the merger, Merck solely possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market until Glenmark entered with a generic on December 12, 2016. After December 12, 2016, Merck shared its monopoly power with Glenmark, and the two companies jointly maintained an illegal monopoly until at least June 12, 2017.

196. As described throughout this Complaint, and at all times relevant to this Complaint, Merck, Schering-Plough, and Schering knowingly and willfully engaged in an illegal conspiracy to monopolize the relevant market by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Zetia from the market. In around 2010, Glenmark and Par joined this conspiracy designed to unlawfully keep AB-rated generic equivalents of Zetia from the market.[16]

197. In furtherance of this conspiracy, Defendants took the following actions:

- By bringing and maintaining patent litigation against Glenmark that Merck later admitted was meritless, failing to disclose prior art to the USPTO during the prosecution of the RE '721 patent, and entering into a reverse payment agreement with Glenmark, Merck, along with Schering-Plough, and Schering, willfully and intentionally maintained, enhanced, and extended its monopoly power through restrictive and exclusionary conduct. Specifically, Merck and Schering-Plough failed to disclose prior art to the USPTO related to the RE '721 patent, brought and maintained frivolous patent litigation, and then effectively paid Glenmark and Par hundreds of millions of dollars to delay the launch of Glenmark's generic

[16] For purposes of clarity, Plaintiff specifically alleges that Merck & Co., Inc. and its subsidiaries acted in concert with Schering-Plough and its subsidiaries at all times before their 2009 merger and continued acting in concert through the time the unlawful settlement agreement was signed with Glenmark. Indeed, Schering-Plough, Schering (a subsidiary of Schering-Plough), Merck & Co., and MSP Singapore LLC (a subsidiary of Merck & Co., Inc.) sought and obtained the Zetia NDA. Schering-Plough and Schering prosecuted the RE '721 patent (and its family members) and conducted research on the metabolites of SCH48461, but did not disclose that research to the USPTO. And Schering and MSP Singapore LLC initiated the baseless patent actions against Mylan and Glenmark related to Zetia, and both companies are signatories to the settlement agreement with Glenmark that contains the No-AG Agreement.

Zetia product so that 100% of the Zetia market was allocated to Merck until December 12, 2016;

- By keeping an authorized generic off the market during Glenmark's 180-day generic exclusivity period, thereby allowing Glenmark to monopolize the generic market for Zetia during this time period;
- Raising and maintaining prices so that Plaintiff paid supra-competitive prices for Zetia; and
- Otherwise conspiring to unlawfully monopolize the relevant market.

198. The goal, purpose, and effect of Defendants' conspiracy was to maintain and extend Merck's monopoly power with respect to Zetia. Defendants' illegal conspiracy allowed Merck to continue charging supra-competitive prices for Zetia, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' scheme allowed Glenmark to reap the benefits of reduced generic competition in the United States.

199. Defendants' conduct violated antitrust and competition statutes of all States and territories that may provide any relief for indirect purchasers/payors, including but not limited to each the following such laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of Zetia, Vytorin, and generic Zetia in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New York;

r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in West Virginia; and

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wisconsin.

200. Defendants' conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

201. Defendants' unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for the drugs at issue paid for, and/or dispensed in each State or territory.

202. Defendants' unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

203. During the relevant period, through either Merck, Glenmark, Par, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

204. There was and is a gross and unconscionable disparity between the price that Humana paid for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Defendants' illegal conduct.

205. As a direct and proximate result of Merck's violation of each of the foregoing laws, Humana has been harmed by paying artificially inflated, supracompetitive prices for Zetia, generic Zetia, and Vytorin dispensed to members throughout the United States, and Humana has suffered damages in an amount to be proven at trial.

COUNT III:
Conspiracy to Restrain Trade in Violation of Various State Antitrust Laws
(All Defendants)

206. Humana incorporates by reference the allegations in Paragraphs 1 through 205, above.

207. On or about May 10, 2010, Merck and Glenmark entered into a reverse payment agreement, the purpose and effect of which was to (a) allocate all sales of Zetia in the United States to Merck; (b) prevent the sale of a generic version of Zetia in the United States, thereby protecting Zetia and Vytorin from generic competition for as many as five years; and (c) effectively fix the prices for Zetia and Vytorin at supracompetitive levels. Although not a signatory to the agreement, Par functionally participated in the agreement and explicitly approved its terms.

208. By entering into the unlawful agreement, Merck, Par, and Glenmark unlawfully conspired in restraint of trade and did restrain trade.

209. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a per se violation.

210. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement was not reasonably necessary to accomplish any procompetitive objective. The agreement included a reverse payment from Merck to Glenmark that exceeded Merck's anticipated litigation costs to continue pursuing the patent litigation. Moreover, any potential justification that Defendants could assert will not

outweigh the substantial anticompetitive effect of their agreement. Even if Defendants could assert a legitimate, non-pretextual, procompetitive business justification for the reverse payment agreement, the anticompetitive effects of the agreement would substantially outweigh any supposed pro-competitive effects of the agreement.

211. Merck, Glenmark, and Par's actions violated antitrust and competition statutes of all States and territories that may provide any relief for indirect purchasers/payors, including but not limited to each the following such laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of Zetia, Vytorin, and generic Zetia in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New York;

r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in West Virginia; and

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wisconsin.

212. Defendants' conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

213. The unlawful acts by Defendants had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for the drugs at issue paid for, and/or dispensed in each State or territory.

214. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

215. During the relevant period, through either Defendants themselves or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

216. There was and is a gross and unconscionable disparity between the prices that Humana paid for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Defendants' illegal conduct.

217. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Humana has been harmed by paying artificially inflated, supracompetitive prices for Zetia, generic Zetia, and Vytorin dispensed to members throughout the United States, and Humana has suffered damages in an amount to be proven at trial.

COUNT IV:
Unfair and Deceptive Trade Practices in Violation of Various State Unfair Competition and Consumer Protection Laws
(All Defendants)

218. Humana incorporates by reference the allegations in Paragraphs 1 through 217, above.

219. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or deceptive acts and practices in violation of the following State laws:

a. Ariz. Code §§ 44-1522, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arizona;

b. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arkansas;

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in California;

d. Colo. Rev. Stat § 6-1-105, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Colorado;

e. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of Zetia, Vytorin, and generic Zetia in the District of Columbia;

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Florida;

g. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Idaho;

h. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Illinois;

i. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Indiana;

j. La. Rev. Stat. Ann. § 51:1401, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Louisiana;

k. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Maine;

l. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Massachusetts;

m. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Michigan;

n. Minn. Stat. § 325D.43, *et. seq.*, Minn. Stat. § 325F.69, *et seq.*, and Minn. Stat. § 8.31, et seq., with respect to purchases of Zetia, Vytorin, and generic Zetia in Minnesota;

o. Miss. Code. Ann. § 75-24-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Mississippi;

p. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Missouri;

q. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nebraska;

r. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nevada;

s. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Hampshire;

t. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Mexico;

u. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New York;

v. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Carolina;

w. N.D. Cent. Code § 51-15-01, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Dakota;

x. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Pennsylvania;

y. S.C. Stat. Ann. § 39-5-10, *et seq.*, for purchases of Zetia, Vytorin, and generic Zetia in South Carolina;

z. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in South Dakota;

aa. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Utah;

bb. 9 Vt. § 2451, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Vermont;

cc. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Virginia;

dd. W.Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in West Virginia;

ee. Wis. Stat. § 100.18; Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wisconsin; and

ff. Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wyoming.

220. The unlawful acts by Defendants had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for the drugs at issue paid for, and/or dispensed in each State or territory.

221. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

222. During the relevant period, through either Defendants themselves or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

223. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Humana has been harmed by paying artificially inflated, supracompetitive prices for the drugs dispensed to members throughout the United States, and Humana has suffered damages in an amount to be proven at trial.

224. There was and is a gross and unconscionable disparity between the price that Humana paid for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Defendants' illegal conduct.

225. Humana has been injured in its business and property by paying more for the drugs at issue than in the absence of Defendants' unlawful conduct and violation of the foregoing laws.

226. Defendants' conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

COUNT V:
Monopolistic Scheme in Violation of Various State Antitrust Laws
(Against Merck)

227. Humana incorporates by reference the allegations in Paragraphs 1 through 226, above.

228. At all relevant times, Merck possessed monopoly power in the relevant markets. Prior to their merger, Merck and Schering-Plough possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market through their joint venture. After the merger, Merck solely possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

229. Through the overarching anticompetitive scheme explained extensively above, Merck, acting in concert with Schering-Plough and Schering (until the time the unlawful settlement agreement was executed) and Glenmark (in reaching the unlawful settlement agreement), willfully maintained its monopoly power in the relevant markets using restrictive or exclusionary conduct, rather than by means of greater business acumen, thereby injuring Plaintiff.

230. It was Merck's conscious objective to further its dominance in the relevant markets by and through the overarching anticompetitive scheme.

231. As stated more fully above, Merck knowingly, willfully, and wrongfully maintained its monopoly power and harmed competition by:

a. Along with Schering-Plough and Schering, failing to disclose prior art to the USPTO and misrepresenting the true inventors, both with the specific intent to deceive the patent examiners, during the prosecution of at least the '115 and RE '721 patents;

b. Causing patents to be listed in the Orange Book that it knew were invalid, unenforceable and/or did not cover Zetia and/or Vytorin;

c. Asserting, along with Schering, the invalid and unenforceable RE '721 and RE '461 patents in baseless lawsuits against generic Zetia and Vytorin manufacturers for the specific purpose to unlawfully delay generic competition; and

d. Entering, along with Schering and Glenmark, into an unlawful agreement with Glenmark wherein Merck paid Glenmark to delay marketing its generic Zetia so that Merck could extend its monopoly and agreed to forego launching a Zetia AG during Glenmark's first-filer exclusivity period.

232. To the extent Merck is permitted to assert one, there is and was no cognizable, non-pretextual pro-competitive justification for Merck's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Merck was permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

233. As a direct and proximate result of Merck's illegal monopolistic conduct, as alleged in this Complaint, Plaintiff was injured.

234. By engaging in the foregoing conduct, Merck intentionally and wrongfully maintained monopoly power in the relevant markets in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of Zetia, Vytorin, and generic Zetia in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in New York;

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in West Virginia; and

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Zetia, Vytorin, and generic Zetia in Wisconsin.

COUNT VI:
Unjust Enrichment Under State Law
(All Defendants)

235. Humana incorporates by reference the allegations in Paragraphs 1 through 234, above.

236. Defendants have benefited from artificial prices in the sale of Zetia, Vytorin, and generic Zetia resulting from the unlawful and inequitable acts alleged throughout this Complaint.

237. Defendants' financial benefit resulting from their unlawful and inequitable acts are traceable to overpayments for Zetia, Vytorin, and generic Zetia made by Humana.

238. Humana has conferred upon Defendants an economic benefit, profits from unlawful overcharges, to the economic detriment of Humana.

239. It would be futile for Humana to seek a remedy from any party with whom it has privity of contract for its indirect purchases of Zetia, Vytorin, and generic Zetia.

240. It would be futile for Humana to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it purchased Zetia, Vytorin, and generic Zetia, as it is not liable and would not compensate Humana for the impact of Defendants' unlawful conduct.

241. The economic benefit of overcharges derived by Defendants through charging supracompetitive and artificially inflated prices for Zetia, generic Zetia, and Vytorin is a direct and proximate result of Defendants' unlawful conduct.

242. The economic benefits derived by Defendants rightfully belong to Humana, as it paid anticompetitive and monopolistic prices during the relevant period, benefiting Defendants.

243. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all States and territories in the United States, except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges for Zetia, generic Zetia, and Vytorin derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

244. Defendants are aware of and appreciate the benefits bestowed upon them by Humana.

245. Defendants should be compelled to disgorge in a common fund for the benefit of Humana all unlawful or inequitable proceeds it received.

246. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants that are traceable to Humana.

DEMAND FOR JUDGMENT

WHEREFORE, Humana demands judgment against Defendants, as follows:

247. Awarding Humana actual, consequential, compensatory, treble, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at the statutory rates;

248. Awarding Humana equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

249. Declaring the acts alleged herein to be unlawful under the State statutes set forth above, and unjust enrichment of the States and territories set forth above;

250. Awarding Humana its reasonable costs and expenses, including attorneys' fees; and

251. Awarding all other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Humana demands a jury trial on all claims so triable.

Dated: February 9, 2022

Respectfully submitted,

/s/ Brett A. Spain

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Counsel for Plaintiff Humana Inc.

CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically send an email notification of such filing to all counsel of record who have filed an appearance.

Dated: February 9, 2022

/s/ Brett A. Spain

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